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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The inventions as claimed are classified into following groups:

I. Claims 1-19 drawn to an expression vector comprising first expression cassette encoding TAF under the control of a TSRE and a second expression cassette encoding a selected polypeptide under the control of a promoter comprising a TSRE and or TBS.

II. Claim 20 drawn to an expression vector comprising first expression cassette encoding TAF under the control of a TSRE and a second expression cassette encoding a selected polypeptide under the control of a promoter comprising a TSRE and or TBS and further comprising a third expression cassette comprising a third coding region that encodes TSI under the control of TSRE and TAB and a fourth expression cassette comprising fourth encoding region under the control of fourth promoter that I negatively regulated by TSI.

III. Claims 21-29 drawn to a method of expressing a selected peptide in a cell of interest comprising expression vector comprising first expression cassette encoding TAF under the control of a TSRE and a second expression cassette encoding a selected polypeptide under the control of a promoter comprising a TSRE and or TBS.

IV. Claim 30 drawn to a method of expressing a selected peptide in a cell of interest comprising expression vector comprising first expression cassette encoding TAF under the control of a TSRE and a second expression cassette encoding a selected polypeptide under the control of a promoter comprising a TSRE and or TBS and further

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comprising a third expression cassette comprising a third coding region that encodes TSI under the control of TSRE and TAB and a fourth expression cassette comprising fourth encoding region under the control of fourth promoter that I negatively regulated by TSI.

V. Claims 31-49 drawn to a method of treating cancer comprising administering a subject having cancer an expression vector comprising first expression cassette encoding TAF under the control of a TSRE and a second expression cassette encoding a selected polypeptide under the control of a promoter comprising a TSRE and or TBS.

VI. Claim 50 drawn to a method of treating cancer comprising administering a subject having cancer an expression vector comprising first expression cassette encoding TAF under the control of a TSRE and a second expression cassette encoding a selected polypeptide under the control of a promoter comprising a TSRE and or TBS and further comprising a third expression cassette comprising a third coding region that encodes TSI under the control of TSRE and TAB and a fourth expression cassette comprising fourth encoding region under the control of fourth promoter that I negatively regulated by TSI.

VII Claim 51 drawn to an expression vector comprising first expression cassette encoding TSI under the control of a promoter under TSI binding site (SBS) for a second TSI and a second expression cassette encoding a selected TAF under the control of a promoter comprising a TSRE and a third expression cassette comprising encoding said second TSI, the third coding region, under the control of a TSRE and a fourth expression cassette comprising fourth coding region under the control of fourth promoter comprising a TAF binding site.

VIII. Claim 52 drawn to a method of expressing a polypeptide in a cell of interest comprising contacting said cell with an expression vector comprising first expression cassette encoding TSI under the control of a promoter under TSI binding site (SBS) for a second TSI and a second expression cassette encoding a selected TAF under the

control of a promoter comprising a TSRE and a third expression cassette comprising encoding said second TSI, the third coding region, under the control of a TSRE and a fourth expression cassette comprising fourth coding region under the control of fourth promoter comprising a TAF binding site.

IX. Claim 53 drawn to a method of treating cancer comprising administering a subject having cancer an expression vector comprising first expression cassette encoding TSI under the control of a promoter under TSI binding site (SBS) for a second TSI and a second expression cassette encoding a selected TAF under the control of a promoter comprising a TSRE and a third expression cassette comprising encoding said second TSI, the third coding region, under the control of a TSRE and a fourth expression cassette comprising fourth coding region under the control of fourth promoter comprising a TAF binding site.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: a) a prior art of record exists regarding a feature linking technical claims 1-43 i.e., an expression cassette encoding a transcriptional activating factor (TAF) under the control of a promoter comprising TSRE and TBS (For example see Wang et al, 1997, Genes Dev. 11:2658-69; Albright et al, 2000, Gene 242:1-13), b) the inventions VII-IX (claims 51-53) do not have the same technical feature of inventions that link the inventions I-IV. The invention as whole thus lacks unity under PCT rule hence a restriction as indicated above is proper. The mode of operation, and the effects evaluated in each of the above invention are distinct and different from the other. Therefore, a search and examination for the patentability of the above inventive groups together would generate an undue search burden on the examiner. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species: Should **Group I** be elected from above, the.

(a). Applicant is required chose a single species of vector among the recited in claims 2 and 5 i.e. a non viral vector or a viral vector.

(b). If Applicant elects viral vector the Applicant is further required chose a single species of a viral vector among the recited in claim 7 i.e., an adenoviral vector or a retroviral vector or a herpesviral vector or a pox virus vector or a polyoma virus vector or an alpha virus vector or an adeno-associated viral vector.

(c). Applicant is required chose a single species of viral vector among the recited in claims 8 and 10 i.e., a replication-deficient viral vector or a replication-competent viral vector or a conditionally-competent viral vector.

(d). Applicant is required chose a single species of TAF among the recited in claim 12 i.e. an antibiotic regulated TAF or a hormone regulated TAF or a human immunodeficiency virus TAF or a hepatocyte TAF.

(e). Applicant is required chose a single species of TSRE among the recited in claims 13 i.e., a an ARR2PB promoter or a probasin promoter or an osteocalcin promoter or a human kallikrein 2 promoter or a DD3 promoter or a Clara cell secretory protein promoter or a liver-type pyruvate kinase proximal promoter or an apoE promoter or an alcohol dehydrogenase 6 promoter or a MUC-1 promoter or a survivin promoter or a CCR5 promoter a PSA promoter or an AFP promoter or an albumin promoter or a telomerase promoter.

(f). Applicant is required chose a single species of anticancer polypeptide character among the recited in claim 16 i.e. a tumor suppressor or an inducer of apoptosis or a cell cycle regulator or an inhibitor of angiogenesis.

(g). Applicant is required chose a single species of therapeutic polypeptide among the recited in claim 17 i.e. a cytokine or a hormone or a tumor antigen or a pathogen antigen.

(h). Applicant is required chose a single species of viral vector among the recited in claim 18 i.e. an Adenoviral vector or a herpes simplex virus.

If Applicant elects Adenoviral vector from above the Applicant is further required to choose a single polypeptide from recited in claim 18 corresponding to the elected vector i.e., an E1 protein or an E2 protein or an E4 protein or a fiber capsid protein or an adenovirus terminal binding protein or an adenovirus polymerase.

If Applicant elects herpes simplex virus vector from above the Applicant is further required to choose a single polypeptide from recited in claim 18 corresponding to the elected vector i.e., herpes virus early gene or herpes virus late gene.

The species are independent or distinct because they are structurally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains claims directed to the following patentably distinct species: Should **Group III** be elected from above, the

(a). Applicant is required chose a single species of vector among the recited in claims 22 and 23 i.e. a non viral vector or a viral vector.

(b). If Applicant elects viral vector the Applicant is further required chose a single species of a viral vector among the recited in claim 24 i.e., an adenoviral vector or a retroviral vector or a herpesviral vector or a pox virus vector or a polyoma virus vector or an alpha virus vector or an adeno-associate viral vector.

(c). Applicant is required chose a single species of viral vector among the recited in claims 25-27 i.e., a replication-deficient viral vector or a replication-competent viral vector or a conditionally-competent viral vector.

(d). Applicant is required chose a single species of TAF among the recited in claim 28 i.e. an antibiotic regulated TAF or ahormone regulated TAF or a human immunodeficiency virus TAF or a hepatocyte TAF.

(e). Applicant is required chose a single species of TSRE among the recited in claims 29 i.e., a an ARR2PB promoter or a probasin promoter or an osteocalcin promoter or a human kallikrein 2 promoter or a DD3 promoter or a Clara cell secretory protein promoter or a liver-type pyruvate kinase proximal promoter or an apoE promoter or an alcohol dehydrogenase 6 promoter or a MUC-1 promoter or a survivin promoter or a CCR5 promoter a PSA promoter or an AFP promoter or an albumin promoter or a telomerase promoter.

The species are independent or distinct because they are structurally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains claims directed to the following patentably distinct species: Should **Group V** be elected from above, the.

(a). Applicant is required chose a single species of vector among the recited in claims 32 and 33 i.e. a non viral vector or a viral vector.

(b). If Applicant elects viral vector the Applicant is further required chose a single species of a viral vector among the recited in claim 34 i.e., an adenoviral vector or a

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retroviral vector or a herpesviral vector or a pox virus vector or a polyoma virus vector or an alpha virus vector or an adeno-associated viral vector.

(c). Applicant is required chose a single species of viral vector among the recited in claims 35-37 i.e., a replication-deficient viral vector or a replication-competent viral vector or a conditionally-competent viral vector.

(d). Applicant is required chose a single species of TAF among the recited in claim 38 i.e. an antibiotic regulated TAF or ahormone regulated TAF or a human immunodeficiency virus TAF or a hepatocyte TAF.

(e). Applicant is required chose a single species of TSRE among the recited in claims 39 i.e., a an ARR2PB promoter or a probasin promoter or an osteocalcin promoter or a human kallikrein 2 promoter or a DD3 promoter or a Clara cell secretory protein promoter or a liver-type pymvate kinase proximal promoter or an apoE promoter or an alcohol dehydrogenase 6 promoter or a MUC-1promoter or a survivin promoter or a CCR5 promoter a PSA promoter or an AFP promoter or an albumin promoter or a telomerase promoter.

(f). Applicant is required chose a single species of cancer among the recited in claim 41 i.e., breastcancer or ovarian cancer or fallopiantube cancer or cervical cancer or uterine cancer or prostate cancer or testicular cancer or pancreatic cancer or colon cancer or bladder cancer or liver cancer or stomach cancer or lung cancer or lymphoid cancer or brain cancer or thyroid cancer or head & neck cancer or skin cancer or leukemia.

(g). Applicant is required chose a single species of route of administration of vectors to a cancer subject among the recited in claims 43 and 44 i.e. intratumorally or into tumor vasculature or local to a tumor or regional to a tumor or regional to a tumor systemically or intravenously or intra-arterially or subcutaneously or intramuscularly or into a natural body cavity or into a artificial body cavity.

(h). Applicant is required chose a single species cancer type among the recited in claim 45 i.e. recurrent cancer or a metastatic cancer or a drug resistant cancer.

(i). Applicant is required chose a single species of distinct cancer therapy among the cancer therapies recited in claim 47 i.e. chemotherapy or radiotherapy or hormonal therapy or immunotherapy or cryotherapy or toxin therapy or surgery or a second gene therapy

The species are independent or distinct because they are structurally and/or clinically distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. Applicant is advised that the reply to this requirement to be complete must

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include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanne Ph.D.*, whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Friday from 9 AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/Robert M Kelly/

Primary Examiner, Art Unit 1633